

REMARKS

Reconsideration and Allowance of the above-referenced application are respectfully requested.

The specification stands objected to under 35 USC 112, first paragraph as allegedly failing how to adequately teach. Withdrawal of the objection is believed to be in order for the reasons that follow.

Claim 12 has been amended to more accurately define the claimed invention. It is well known in the art that probes of at least 15 nucleotides in length or of at least 30 nucleotides with at least 60% homology can be used in hybridization studies.

Claim 14 cites the detection of amplification rearrangement or over-expression. Amplification rearrangement results in additional copies of the gene in the genome while over-expression results in additional copies of mRNA.

As a result of the above-stated reasons, the applicants submit that the specification adequately teaches the claimed invention. Reconsideration is requested.

Claims 12-32 stand rejected under 35 USC 112, first paragraph, for the reasons set forth in the objection to the specification. Withdrawal of the rejection is believed to be in order for the above-described reasons.

Claims 12-32 stand rejected under 35 USC 112, second paragraph as allegedly being indefinite. Withdrawal of the rejection is believed to be in order for the reasons that follow.

Claim 12 has been amended to more accurately define the claimed invention. The phrase "at least a part of a gene..." has been amended to "at least 15 contiguous nucleotides of or at least 30 contiguous nucleotides with at least 60% homology of". The sequence is presented 5' to 3'; this is standard in the art.

Claim 13 has been amended to more accurately define the claimed invention. The use of multiple probes has been changed to at least one probe. Multiple probes could be used to ensure the accuracy of the test.

Claim 14 has been amended such that it does not depend on a cancelled claim or refer to a non-elected invention.

New claim 33 has been added to replace cancelled claim 15. Applicants believe the new claim is in condition for allowance. Consideration is requested.

Claim 16 has been amended to more accurately define the claimed invention. "Amino acid seequence" has been replaced with "Nucleotide sequence". "a fragment thereof" has been defined as stated above for the nucleic acid probes.

The phrase "a carrier" in claims 17 and 21 are defined in the art as a substance which contains or holds the claimed composition.

Claim 21 has been amended to correct the typographical error.

The claims as presented are believed to be definite. Accordingly, withdrawal of the rejection is requested.

Claims 31 and 32 stand rejected under 35 USC 112, fourth paragraph as allegedly being of improper dependent form. Although claims 31 and 32 have been cancelled, applicants would like to note that claim 26 does not specify that a labeled nucleic acid sequence be used nor does claim 26 specifically mention in situ hybridization.

Claims 12-32 stand rejected under 35 U.S.C. 101 because the utility of detecting cancer is allegedly not demonstrated. The Examiner states that "Possibly the entire cited sequence may have the stated utility but the critical probes having the utility if they are over a certain size and sequence is not demonstrated". The critical probes have been defined in the amended claims such that they are of utility. It is well known in the art that a probe of at least 15 contiguous nucleotides or at least 30 contiguous nucleotides with at least 60% homology will serve as a probe for Southern blot and northern blot analysis.

Additionally, the Applicants would like to draw the Examiner's attention to Figures 6, 7, and 8 of the instant specification. Figure 6 shows the overexpression of MAC117 in

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RNA in human mammary tumor cell lines by northern blot analysis. Figure 7 shows the 185-kDa protein specific for MAC117 and its overexpression in human mammary tumor cell lines. Figure 8 shows the amplification of MAC117 in 4 mammary tumor cell lines by Southern blot analysis.

Further, the Applicants would like to draw the Examiner's attention to King et al. (1985) Science 229:974-976; Kraus et al. (1987) EMBO J. 6:605-610; DiFiore et al. (1987) Science 237:178-182; Lacroix et al. (1989) Oncogene 4:145-151; and Slamon et al. Science 235:177-182. These references clearly show the amplification and overexpression of the novel V-erbB-related gene (designated as erb-2 in some papers) in human mammary cells. Accordingly, Reconsideration is requested.

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In view of the foregoing, it is respectfully submitted that all Applicants' claims are in acceptable form and define patentable invention over the art of record. Accordingly, favorable consideration and Allowance are respectfully requested.

Respectfully submitted,
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